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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,477	01/18/2002	Michael C. Stewart	26448-05730	5572

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EXAMINER	
KASZTEJNA, MATTHEW JOHN	
ART UNIT	PAPER NUMBER
3739	

MAIL DATE	DELIVERY MODE
08/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/054,477	STEWART ET AL.	
	Examiner	Art Unit	
	MATTHEW J. KASZTEJNA	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *84,95,103,123 and 125* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *84,95,103,123 and 125* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 1, 2008 has been entered.

Notice of Amendment

In response to the amendment filed on July 9, 2008, amended claims 84, 95, 103 and 125 and canceled claims 93, 99, 110, 112, 122 and 124 are acknowledged. The current rejections of the claims are *withdrawn*. The following new grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 84, 95, 103 and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,817,061 to Goodwin et al. in view of U.S. Patent No. 5,776,112 to Stephens et al.

In regards to claims 84 and 125, Goodwin et al. disclose a tissue dissector comprising: an elongated tube 13 having a central axis extending between a proximal end and a distal end and enclosing an endoscopic imaging element 24 (see Col.5, Lines 2-5); and a dissecting, viewing and dilating unit 15 removably mounted on the distal end of the tubular body (see Col. 4, Lines 10-18), including; a transparent distal tip 17 having substantially conical tapered outer walls converging with conical symmetry about the central axis to a blunt end for dissecting tissue, the tip being disposed on a distal end of the dilating unit to dissect tissue and facilitate passage of the tubular body through tissue under visualization through the tip by the endoscopic imaging element (see Fig. 2 and Col. 4, Lines 26-32). Goodwin et al. are silent with respect to the dilating element having a substantially olive-shaped exterior contour that is disposed with rotational symmetry about the central axis and that gradually increases in cross-sectional dimension symmetrically about the central axis in the proximal direction from a distal edge thereof to a maximum cross-sectional dimension greater than the cross-sectional dimension of the distal end of the tubular body, the dilating element then decreasing in size-cross-sectional dimension symmetrically about the central axis in the proximal direction to a proximal edge for facilitating atraumatic expansion of tissue following dissection by the tapered distal tip during advance of the tissue dissector through tissue. Stephens et al. teach of an analogous apparatus comprising an obturator assembly 22 having a piercing tip 30 encased within a safety shield 27 (see Figs. 2-4). The piercing tip of the obturator is attached to the distal end of the obturator (similar to the apparatus of Goodwin et al. wherein the dilating unit 15 is attached to the

end of an obturator assembly 11). **In regard to claim 125,** the safety shield of the obturator assembly has a wall 39 which defines shield diameter. The shield diameter is designated as D in FIG. 4. As illustrated in FIG. 4, diameter, D, of the safety shield taken in a plane parallel to the planar surfaces of the piercing tip is substantially greater than the base width, W_1, of the piercing tip. Illustrating this particular feature of the invention further, FIG. 8 shows that the safety shield contains a blade slot 40 for receiving the piercing tip of the obturator within the safety shield. As depicted in FIG. 8, the size of the blade slot is substantially less than the diameter of the safety shield (see Col. 4, Lines 46-67). An olive-shaped exterior of the dilating element can clearly be seen in Figures. 5, 7-8 and 12-13. It would have been obvious to one skilled in the art at the time the invention was made to construct the dilating element of Goodwin et al. to be olive-shaped and greater in diameter than the distal end of the tubular body to promote smooth expansion and dilation of tissue during insertion and withdrawal (see Col. 5, Lines 5-10) as taught by Stephens et al. Furthermore, it would have been beneficial to use the safety shield in the apparatus of Goodwin et al. to cover the cutting edge surface of the piercing tip of the obturator and thus prevent inadvertent puncture (see Col. 4, Lines 50-52)., which is also taught by Stephens et al.

In regards to claim 95, Goodwin et al. disclose a tissue dissector, wherein the dilating element 15 is flexible in cross-sectional dimension. In the broadest interpretation of the claim, the term “flexible” merely means capable of being bent without breaking. All materials are capable of being bent to a certain degree.

In regards to claim 103, Goodwin et al. disclose a tissue dissector, wherein the distal tip 15 and the dilating element 17 are formed as a single unit removably mounted on the tubular body substantially symmetrically about the central axis. The safety shield 27 of Stephens et al. is also formed as a single unit, including dilating elements 41, 42, removably mounted on the tubular body symmetrically about the central axis.

Claim 123 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,817,061 to Goodwin et al. in view of U.S. Patent No. 5,776,112 to Stephens et al. in further view of U.S. Patent No. 5,688,286 to Yoon.

In regards to claim 123, Goodwin et al. and Stephens et al. disclose a tissue dissector having a removable dilating unit attached to the distal end of the flexible tube (see above rejection) but are silent with respect wherein the tip is resiliently compressible. Yoon teaches of an analogous medical apparatus wherein distal end 34/64 as illustrated in Figs. 4-6 and 19-20 is formed of a resilient, flexible, compressible and expandable material that can fold or wrinkle, the material defining a curved wall (see Col. 12, Lines 8-15). Furthermore, the safety shield is made from a cylindrical length of a rigid or flexible material such as stainless steel or plastic dependent upon use of the safety trocar penetrating instrument (se Col. 5, lines 38-41). Additionally, by forming the portal sleeve, the trocar and the safety shield from a flexible material, the safety trocar penetrating instrument can be inserted through non-linear anatomical passages. It would have been obvious to one skilled in the art at the time the invention was made to construct the dilating element in the apparatus of Goodwin et al. and Stephens et al. from a resilient material so the material itself can provide a bias for

returning the safety shield to the extended position upon removal of force from tissue contact as taught by Yoon.

Response to Arguments

Applicant's arguments with respect to claims 84, 95, 103, 123 and 125 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./
Examiner, Art Unit 3739

8/18/8